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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,964	12/12/2000	Konstantin Petrukhin	20177YP	8195

210 7590 08/13/2003

MERCK AND CO INC
P O BOX 2000
RAHWAY, NJ 070650907

EXAMINER	
SCHNIZER, HOLLY G	

ART UNIT	PAPER NUMBER
1653	9

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No. 09/622,964	Applicant(s) PETRUKHIN ET AL.	
	Examiner Holly Schnizer	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *7-13,18 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *4 and 14-17* is/are rejected.

7)☐ Claim(s) *1-6 and 14-17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6 and 14-17, drawn to DNA, expression vectors, host cells, and a method of diagnosis using DNA, classified in class 536, subclass 23.1.

Group II, claims 7-12, drawn to a CG1CE protein, classified in class 530, subclass 300.

Group III, claim(s) 13, drawn to an antibody, classified in class 424, subclass 130.1.

Group IV, claim(s) 18-19, drawn to a method of determining whether a substance is an activator or inhibitor of CG1CE, classified in class 435, subclass 4.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first recited product, the isolated DNA encoding a CG1CE protein, a vector and host cell comprising the DNA, and a method of diagnosis using the DNA. Further, pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention.

During a telephone conversation with Vineet Kohli on July 30, 2003, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-6 and

14-17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-13 and 18-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Status of the Claims

Claims 1-19 are pending. Claims 7-13 and 18-19 are withdrawn from consideration as being drawn to non-elected subject matter and Claims 1-6 and 14-17 have been examined on the merits in this Office Action.

Drawings

The drawings are objected to for the reasons cited on the attached Form PTO 948.

The examiner also objects to the drawings because the sequence identifiers in Figure 7 appear to be incorrect. For example, the first and second sequences (protein sequences) appear to be given the sequence identifiers SEQ ID NO: 2 and 28, respectively. However, SEQ ID NOs: 2 and 28 are nucleotide sequences and the sequences in the figures are protein sequences. In addition, the figure refers to SEQ ID

NOs: 32-43, however there are only 31 sequences in the sequence listing. Patent applications which contain disclosures of nucleotide and/or amino acid sequences must contain a sequence listing disclosing the nucleotide and/or amino acid sequences. Where the description or claims of the application discuss a sequence that is set forth in the Sequence Listing, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the application (see 37 C.F.R. 1.821(a)-(e) and MPEP 2422). It is noted that sequences of the length shown in Figure 7 do not appear in the Sequence Listing. Correction is required.

Objections

It is noted that Claim 3 contains a typographical error in line 2. The word "different" is misspelled as "differennt". Correction is requested.

Claims 1-6 and 14-17 should refer to the sequence identifier as "SEQ ID NO:" rather than "SEQ. I.D. NO.:". Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the interim guidelines on written Guidelines published January 5, 2001 in the Federal Register, Vol. 66, No. 4, p. 1099-1111 (available at www.uspto.gov) and the Examiner training Materials on Written Description also available at www.uspto.gov.

The claim is drawn to a genus of isolated DNA molecules that hybridize with at least one of SEQ ID NO: 1, SEQ ID NO:2, SEQ ID NO:4, or SEQ ID NO:28. There is no limitation on the function of the protein encoded by the claimed DNA or the length of the claimed DNA. Therefore, the claimed genus includes nucleic acid sequences of widely varying sequences and lengths and sequences encoding proteins having any function.

A review of the full content of the Specification indicates that the essential feature of the invention is the discovery of human and mouse DNA encoding a CG1CE protein wherein certain mutations in the DNA were found to be associated with the development of Best's macular dystrophy. The Specification does not provide any information concerning the function of the encoded protein and the prior art appears to indicate that the protein function was not known at the time of the invention (see Petrukhin et al. Nature Genetics (1998) 19: 241-247 at p. 244, Col. 1, last sentence of 1st paragraph). Two mutations in the DNA encoding CG1CE were found to be

associated with Best's disease. Members of a family who had the disease had a mutation at position 383 of SEQ ID NO:2 whereas a normal family member and 50 other normal unrelated individuals did not have the mutation. In a separate family, two members with the disease had a mutation at position 357 whereas 50 normal unrelated individuals did not have the disease. Therefore, the Specification describes two mutations that could possibly be used as predictors of Best's disease. However, the Specification does not describe any other mutations that are associated with the disease nor what sequence changes would affect the function of the protein (and thereby lead to disease). The Specification does not provide any identifying distinguishing features of the CG1CE DNA that would allow one to recognize which DNA molecules, of all of the nucleic acid molecules that would hybridize to the claimed DNA, would be present in a patient having Best's disease (other than the two mutations described) and which would be present in a healthy individual; or which of the DNA molecules would encode a functional CG1CE and which would encode a non-functional protein or a protein having a different function. Therefore, the written description requirement is not satisfied for the claimed genus of DNA molecules.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is indefinite because the claim is unclear as to when a patient would be considered as having a mutation in the CG1CE gene. If the patients DNA sample has the sequence of SEQ ID NO:2 it would have a different nucleotide sequence relative to SEQ ID NO:4. Likewise, if the patients DNA sample has the sequence of SEQ ID NO:4, it would have a different nucleotide sequence relative to SEQ ID NO:2. Therefore, the method would only have one result—all DNA sequences would be considered to have a mutation in the CG1CE gene. Alternatively, if the claimed method intended to compare sequences to both SEQ ID NO:2 and 4 (wherein all sequences that are not SEQ ID NO:2 or 4 are considered to indicate that the patient carries a mutation in the CG1CE gene) then clarification of the claim language is required.

Claim 15 is rejected because it depends from itself therefore it is unclear as to what DNA sample the claim refers. In the interest of compact prosecution, in this Office Action, Claim 15 has been considered to be dependent from Claim 14. Correction of dependency is required.

Claim 16 is indefinite because it depends from Claim 15. However, a DNA sample that is genomic DNA (of Claim 15) and a DNA sample that is cDNA (of Claim 16) are mutually exclusive. Therefore, the identity of the DNA sample of Claim 16 is unclear. In the interest of compact prosecution, Claim 16 has been considered as dependent from Claim 14 in this Office Action. Correction of claim dependency is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al. (Nature (1995) 377(6547 Suppl.) pp. 3-174). A sequence alignment between SEQ ID NO:1 and a cDNA from Adams et al. (EST19416) is attached to this Office Action.

Adams et al. describe the generation of partial cDNA sequences. A sequence alignment between the sequence EST19416 (Acc. No. AA317489), identified in Adams et al., and SEQ ID NO:1 shows that EST19416 is 86% identical to SEQ ID NO:1 and contains at least 18 consecutive nucleotides of SEQ ID NO:1 (see 100% match of nucleotides 30-60 of database sequence to SEQ ID NO:1). Due to the high degree of similarity between the Adams et al. sequence and SEQ ID NO:1, the Adams et al. sequence would hybridize to a polynucleotide of SEQ ID NO:1. Moreover, the Adams et al. sequence is considered patentably indistinguishable from an oligonucleotide probe comprising at least 18 contiguous nucleotides of SEQ ID NO:1.

Claims 4 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by the Pharmacia Molecular and Cell Biology Products Catalog (1994).

The Pharmacia Catalog provides poly-T primer/probes which would hybridize under stringent conditions to the poly-A sequences found at the end of the sequences of SEQ ID NOs: 2, 4, and 28 of the present invention. The poly-A primer/probes described therein contain at least 18 contiguous nucleotides of SEQ ID NOs: 2, 4, and 28 of the present invention. Therefore, the probes, readily available from Pharmacia, anticipate present Claims 4 and 17.

Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by the Boehringer Mannheim Biochemicals Catalog (1997).

The Boehringer Mannheim Catalog provides a hexanucleotide mix comprising a mixture of hexamer polynucleotides of all possible sequences for random-primed DNA labeling. Therefore, the mixture would contain hexamers perfectly complementary to any 6 nucleotides of the sequences of SEQ ID NOs: 1, 2, 4, or 28 and therefore the hexamers would hybridize to any of the claimed sequences.

Related Art Cited but Not Relied Upon

Marquardt et al. (Human Molecular Genetics (Sept. 1998) Vol. 7, No. 9, pp. 1517-1525) describes a polynucleotide encoding a protein with only 1 amino acid difference from the amino acid sequence of SEQ ID NO:3 of the present invention. It is noted that the publication date occurs after the priority date of the present invention.

Conclusions

Claims 1-3, 5-6, and 14 appear to be free of the prior art of record.. Claims 1-6 and 14-17 are objected to and Claims 4 and 14-17 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-3722. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The Official fax phone number is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

HS

Holly Schnizer
August 5, 2003

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600